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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,292	08/05/2003	Karen M. Haberstroh	3220-73239	7977
23643 7590 08/20/2008 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204				
EXAMINER HANLEY, SUSAN MARIE				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
08/20/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/634,292

Applicant(s)

HABERSTROH ET AL.

Examiner

SUSAN HANLEY

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-19 and 33-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-19 and 33-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/08 has been entered.

Claims 1-5, 7-19 and 33-42 remain under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-5, 7-19 and 33-42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Webster.

Applicant asserts that based on the disclosure at see column 5, lines 31-35 Webster is limited to nanostructured ceramics and fails to teach or suggest a composition that comprises a nanotextured polymeric material as claimed in the present invention.

Applicant asserts that Webster teaches a procedure for forming nanostructured ceramic materials that is not applicable for forming other nanostructured materials. Applicant refers to the preparation of the nano-grained ceramic materials which are produced by precipitating of the ceramic materials using controlled reactions. There

is no disclosure relating how to prepare polymeric materials that display nano-textured surfaces. Applicant concludes that Webster does not provide any guidance of how to prepare such polymeric materials that display nano-sized surface features and a surface roughness of about 50 nm or greater.

Applicant submits that one would not be motivated to prepare a composition comprising a nano-structured polymeric material based on the results disclosed by Webster and there is no reasonable expectation that a polymeric material could substitute for ceramic materials to produce similar results as those obtained with ceramic materials.

Applicant cites Exhibit A; Kim et al, Biomaterials 27 (2006) p 1399-1409) and submits that that the substitution of polymeric materials for ceramic materials is highly variable and does not provide a reasonable expectation of success when using polymeric instead of ceramic materials.

Applicant asserts that Webster is devoid of any suggestion regarding the modification of any polymer component that is also present in the composition and that the presently claimed invention requires a nanostructured polymeric material as an element of the composition and Webster allegedly fails to consider or suggest that a polymer surface could be modified to display nanotextured surface. Applicant contends that above one of ordinary skill in the art would not have a reasonable expectation of success duplicating the results obtained for nanostructured ceramic materials when-

using polymeric materials. Applicant asserts that a surface roughness of about 50 nm or greater are surprising and unexpected.

Applicant asserts that the specification and the Declaration by Dr. Webster demonstrates that polymeric surfaces displaying surface features having dimensions less than 100 nm display unexpected properties relative to the properties displayed by polymeric compositions having submicron or larger surface features and that there was simply no reasonable expectation that polymeric materials would exhibit such properties prior to applicants' invention. Applicant asserts that Webster fails to teach or suggest that a composition comprising nanostructured polymeric material as its active agent would be desirable. Nor does that reference enable the preparation of such compositions.

Applicants note that claim 37 specifically excludes the inclusion of ceramic materials in the presently claimed invention and Webster fails to teach or suggest an implant that lacks the ceramic supporting structure.

Responding to applicant's argument that Webster is limited to nanostructured ceramics and fails to teach or suggest a composition that comprises a nanotextured polymeric, In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., nanotextured) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding applicants statement that Webster is limited to nanostructured ceramics,

Webster discloses at col. 5, lines 41-63 that the composition can comprises a mixture of various percentages of ceramic and polymeric material. This disclosure meets the current claim language because it is "open." The use of the term "comprising" allows for the presence of non-claimed materials in the composition.

Responding to Applicant's assertion that Webster teaches only methods to make ceramic materials, again the transitional language for the claimed nanostructured material is 'open' and allows for the inclusion of non-claimed elements. As demonstrated *supra*, Webster teaches a composite of polymer and ceramics. Furthermore, the method of making a material or composition does not limit or reflect on the material produced as long as the material produced meets the claimed language *supra*. Responding to Applicant's assertion that Webster does not provide any guidance for preparing such polymeric materials that display nano-sized surface features and a surface roughness of about 50 nm or greater, the instant claim language is open and the disclosure of a nanostructured material comprising a polymeric material and a ceramic material meets the claim language. Webster teaches surface roughness at Table 2.

Regarding Applicants statement that the ordinary artisan would not be motivated to prepare a composition comprising a nano-structured polymeric material based on the results disclosed by Webster and there is no reasonable expectation that a polymeric material could substitute for ceramic materials to produce similar results as those obtained with ceramic materials the instant claim language is open and the disclosure of

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a nanostructured material comprising a polymeric material and a ceramic material meets the claim language. The substitution of a polymeric material for a ceramic material is irrelevant due to the instant claim language since Webster discloses a nanostructure having both ceramic and polymer materials which combination meets the claim language. This rebuttal also responds to Applicant's citation of Kim which is related to said substitution.

Responding to Applicant's argument that Webster allegedly fails to consider or suggest that a polymer surface could be modified to display nanotextured surface and that there is no reasonable expectation of success duplicating the results obtained for nanostructured ceramic materials when using polymeric materials: To reiterate, the claim language is open and allows for the inclusion of additional materials not specified in the claim. There is no basis for substituting polymeric material for ceramic materials because the claims are not strictly limited to polymeric material. Regarding Applicant's assertion regarding a nanotextured surface, said phrase is not a claimed element.

Regarding Applicant's assertion that a surface roughness of about 50 nm or greater is surprising and unexpected and that said results are demonstrated in the specification and Dr. Webster's declaration, the opinion declaration was carefully considered and has been given the proper weight with respect to the claimed subject matter as is proper for a declaration that is without objective evidence. An assertion of unexpected results requires the following:

716.02(e) Comparison With Closest Prior Art

An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject

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matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). "A comparison of the claimed invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." In re Merchant, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, In re Finley, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. In re Armstrong, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential). Neither the specification nor the declaration provide such a comparison.

Applicants note that claim 37 specifically excludes the inclusion of ceramic materials in the presently claimed invention. This appears to be the case and claim 37 has been withdrawn from this rejection.

Claim 2 is rejected because the use of the phrase "about 50 nm", for example allows for an unspecified range above and below the reference value. Hence, the claimed dimensions are optimized parameters.

Claim 4 is rejected because the composition is claimed as a whole and the employment of product by process language (e.g., chemical treatment) fails to distinguish the prior art composition from that which is claimed.

Double Patenting

Claims 1-5 and 7-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7 – 20 of copending Application No. 10/362,148.

Claims 1 –5, 7-12 and 18 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 11 of copending Application No. 10/793,721.

Applicant has requested that these rejections be held in abeyance until patentable subject matter is determined.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 has been amended to "consisting of" transitional language. Consisting of is a closed phrase that strictly limits the scope of the claim to what is claimed. However, the claim also recites "about" with respect to the dimension ranges. There is no disclosure that specifies an upper and lower bounds for these ranges. Therefore "about" is open claim language. The juxtaposition of closed language followed by open

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language that allows for any possible dimension is confusing because it is unclear which phrase controls the breadth of the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651